



October 23, 2007

DCH and Open Access to Mental Health Drugs:

The Department of Community Health (DCH) is committed to providing access to all necessary medications in a manner that ensures clinically appropriate, cost-effective therapies are available to our patients. Through the Fee-for-Service Medicaid program, DCH is confident that mental health patients are receiving the medications that are necessary for appropriate treatment.

- DCH has included mental health drugs in its Medicaid Fee-for-Service (FFS) preferred drug list (PDL) since 2004
- All mental health drugs are accessible in the FFS Medicaid program
- Prior authorization is a tool used to ensure clinically and fiscally appropriate use of medications
- The vast majority of mental health medications are available without prior authorization on the FFS PDL
- DCH data shows no increase in utilization of other health care resources (ex. hospitalizations, emergency room visits, outpatient visits) for patients impacted by the PDL
- Additionally, disenrollment from Medicaid due to incarceration has not increased since inclusion of the mental health drugs in the PDL

Open Access to Mental Health Medications in the Georgia Medicaid Fee-for-Service (FFS) Population

Background

The Medicaid drug rebate program is a directive of the Centers for Medicare and Medicaid Services (CMS), which requires manufacturers to pay rebates on pharmaceuticals as a condition for coverage of the medication in the Medicaid program. The Federal Rebate program began in 1991, and currently includes approximately 500 manufacturers. The rebate percentages are on an average 15.1 percent for branded products and 11 percent for generics. In March 2004, the State implemented a Supplemental Rebate Program as part of our Preferred Drug List (PDL) effort. Medications are identified as preferred or non-preferred on the PDL. Supplemental rebates are drug rebates paid to the State in addition to those required by CMS.

Non-preferred drugs subject to the supplemental rebate program typically require prior authorization. Non-preferred medication requests denied through the initial prior authorization request are still available through both the first and second level appeal process.

Drug Evaluation Process

The process by which drugs are evaluated for status on the PDL relies on both clinical and fiscal factors.

Clinical

An evaluation of the clinical aspects of the medication is the first step in the review process. A review of the clinical literature and evidence is conducted. Parties providing input to the clinical evaluation process include but are not limited to the following:

- DCH Clinical Team (Pharmacists and Physicians through Georgia Medical Care Foundation (GMCF))
- NorthStar HealthCare Consulting (Pharmacists and Physician)
- SXC Health Solutions (Pharmacists)
- First Health Clinical Team (Pharmacists)
- Drug Utilization Review (DUR) Board (Pharmacists, Physicians, Dentist, Consumer Advocate)
- Manufacturers
- Consumers/Advocates/Providers (Consumer Comment Meeting)

Utilizing the literature, clinical evidence and the above resources, DCH first determines if a medication is safe and effective. Then, the medication is reviewed based on its clinical advantage(s) over other medications in the same therapeutic category or used to treat the same disease state. Medications that are safe, effective, and possess significantly superior clinical advantages for the entire population may be awarded preferred status without fiscal review.

Fiscal

Several fiscal factors are reviewed by DCH during the PDL evaluation process. First, DCH's actual historical experience with the medication or class of medications in the market is considered. These factors include but are not limited to the following:

- Number of members with prescriptions for the drug
- Number of prescriptions
- Quantity per prescription dispensed by the pharmacy
- Amount paid to the pharmacy

Then, the amount paid is reduced by the CMS rebate amount. Finally, the cost of the prescriptions is further reduced by the supplemental rebate offered by the manufacturer (if any) to arrive at a final net cost of the medication. This process allows DCH to evaluate the net cost per prescription based on actual historical market experience.

Last, the operational/administrative costs (ex. prior authorization/appeal costs, staffing, etc.) and other Medicaid costs are incorporated into the evaluation process. These other Medicaid costs may include the cost of additional office visits, laboratory tests, or other monitoring that must accompany any medication therapy change. An estimated disruption impact from a provider and patient standpoint are also factors that are considered.

Inclusion of Mental Health Drugs

As with many other disease states, the treatment of mental illness is complex. However, the pharmacological approach is similar to medication selection in other disease states. The physician evaluates the patient, co-morbid conditions, concurrent medication regimen(s), a drug's mechanism of action, historical treatment success, side effects, allergies, contraindications, and precautions. As such, medications used to treat Attention Deficit Hyperactivity Disorder (ADHD), depression, bipolar, and schizophrenia are included in the DCH PDL evaluation process. If the provider has no predictors of response to a particular medication, DCH asks the provider to use a preferred medication prior to using a non-preferred medication. If there are predictors of success with a non-preferred medication, those facts must be presented to the Department through the PA process.

Prior to inclusion of the mental health medications in the PDL process and to minimize the impact to patients previously stabilized on mental health medication therapies, DCH grandfathered current users receiving non-preferred medications in these categories. In fact, any patient who had received a single claim for a non-preferred atypical antipsychotic medication within the previous 12 months was exempted from the non-preferred edit. Patients naïve to therapy with a non-preferred mental health drug had to obtain a prior authorization to receive that product. Patients new to Medicaid but established on a non-preferred agent did require a prior authorization. Basically, this process consisted of the physician faxing a statement to DCH's vendor stating the patient had been stabilized on the non-preferred medication, is responding to therapy, and needs to continue therapy. Upon receipt of the appropriate supporting documentation, the request was approved.

Past the prior authorization criteria and reasons stated above, non-preferred medications require medical justification from the provider as to the reason the preferred products are not acceptable for a particular patient. The criterion also allows patients established on a non-preferred agent as part of an in-patient stay to continue that therapy as an outpatient.

Mental Health Preferred Drug List

Very few mental health drugs require prior authorization. Only one antidepressant requires prior authorization. In the atypical antipsychotic category, aripiprazole and olanzapine (single entity and combination product) require prior authorization while risperidone, quetiapine, ziprasidone, paliperidone, and clozapine are available without it. Orally disintegrating and injectable formulations of atypical antipsychotics also require prior authorization. DCH has 15 ADHD medications listed as preferred. Only methylphenidate patches, lisdexamfetamine, atomoxetine, and methamphetamine require prior authorization for children. All ADHD medications require a documented diagnosis of adult ADHD if the recipient is over 21 years of age. DCH contends the Medicaid FFS PDL has very few prior authorizations on mental health medications. (Note: Quantity limitations that meet or exceed the FDA-approved dosing regimens for the mental health medications apply to all mental health medications.)

Prior Authorization

Prior authorization is necessary to ensure:

- clinical appropriateness
- drug safety and avoidance of drug-drug interactions
- reduction in medication errors

- compliance with nationally recognized clinical guidelines from national medical associations
- appropriate monitoring and control of utilization of new drugs or new uses for existing medications
- detection of patients receiving medications from multiple prescribers
- detection and prevention of substance abuse (ex. anti-anxiety medications, etc.)

The prior authorization desk is open Monday through Friday from 8 a.m. until 8 p.m. eastern time and from 9 a.m. until 5:30 p.m. on Saturdays. While the prior authorization desk is closed on Sundays and holidays, representatives and pharmacists are available through the technical call center 24 hours per day, seven days per week, including holidays.

The prior authorization call centers currently answers phone calls within 56 seconds, and the average call lasts just under six minutes.

The prior authorization process includes the initial prior authorization review as well as two additional levels of appeal. The initial prior authorizations are handled while the caller is on the phone. Thus, the turnaround time for these requests averages about 6 minutes. The second level appeals are turned around within two business days of receipt. The second level appeals are handled within three business days of receipt.

Mental Health Drugs: Impact

DCH included the mental health drugs with the commitment that we would monitor the impact and make sure we were not 1) harming patients or 2) shifting costs through the use of other more costly health care resources. Since payment for mental health services resides within both DCH and DHR, coordination of data exchange between the two departments was required. Data from 12 months prior to August 2004 (baseline period) was compared to the post August 2004 time period. The group analyzed was Medicaid-eligible members who received mental health drugs. Findings showed the following:

- The number of admissions to state mental health facilities has not increased
- The length of stay for these patients admitted to a state mental health facility has not increased
- The number of incarcerations among the patients receiving mental health drugs has not increased
- The number of Medicaid emergency department visits had not increased
- The number of Medicaid hospitalizations did not increase
- The number of Medicaid hospital days did not increase
- The number of Medicaid ambulatory care visits did not increase
- The number of mental health medication claims did not increase

DCH worked closely with DHR on this effort to obtain necessary data to ensure cost-shifting to DHR was not occurring. Additionally, no data exists in any agency that directly demonstrates any negative impact of the inclusion of mental health medications in the Medicaid FFS PDL.

Conclusion

The PDL and supplemental rebate efforts have provided a clinically appropriate PDL with substantial savings to the State. The savings from the PDL and supplemental rebate programs come from two sources - the discounts the manufacturers provide to DCH which are collected in the form of supplemental rebate checks AND the market share movement away from higher cost medications to less costly, clinically effective alternative medications. DCH has successfully included mental health medications in PDL with no apparent cost-shifting within the Medicaid program or to DHR or other areas. The current Medicaid FFS PDL lists the vast majority of mental health drugs as preferred without a prior authorization requirement. Access to non-preferred medications can be obtained through the prior authorization and appeal processes. Peer-reviewed clinical studies, practice guidelines, clinical evidence, and the merit of the drugs continue to be evaluated by DCH clinicians, the DUR Board, and DCH clinical vendors. DCH maintains that the current system utilized to deliver much needed pharmaceuticals to the mental health recipients is an open access system whereby recipients are able to access any necessary mental health medication.

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